A double blind, placebo controlled study to assess the safety and efficacy of PCD-04 as a protective agent against anthracycline-induced cardiotoxicity.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21418

Source
Nationaal Trial Register

Brief title
PROTACMI

Health condition

Breast cancer patients.

Sponsors and support

Primary sponsor: LTT Bio-Pharma Co.
Ltd.Atago Green Hills MORI Tower 26F2-5-1, Atago
Minato-ku, Tokyo
105-6201 Japan

Intervention

Outcome measures

Primary outcome

Assessment of safety:

this include evaluation of general safety (Blood pressure, heartrate, monitoring of the patient during infusion, laboratory tests, urinalysis).

Pharmacokinetics:

PSD-04 plasma concentrations during study days.

Pharmacodynamics (primary):

Echocardiography: Left ventricular diastolic function parameters and ejection fraction.

Secondary outcome

Pharmacodynamics (secondary):

1. Biochemical markers for myocardial damage;

2. ECG parameters.

Study description

Background summary

N/A

Study objective

Subjects in the PCD-04 arm will show less anthracyclin-induced cardiotoxicty then subjects in the placebo arm.

Study design

N/A

Intervention

The patients are either randomised in the PCD-04 group or in the placebo group.

Contacts

Public
Center for Human Drug Research,
Zernikedreef 10
F.J.F. Broeyer
Zernikedreef 10
Leiden 2333 CL
The Netherlands
+31 (0)71 5246431
Scientific
Center for Human Drug Research,
Zernikedreef 10
F.J.F. Broeyer
Zernikedreef 10
Leiden 2333 CL
The Netherlands
+31 (0)71 5246431

Eligibility criteria

Inclusion criteria

1. Female;

2. Willing and able to give written informed consent;

3. Between 20 – 75 years of age;

4. Scheduled for the current clinical routine protocol for adjuvant chemotherapy for carcinoma of the breast consisting of doxorubicin / cyclophosphamide cycles.

Exclusion criteria

1. Patients with indication of distant metastases of breast carcinoma;

2. Inability to obtain a good quality echocardiogram before study drug administration;

3. Patients who are unable to remain in supine condition for more than 1 hr;

4. Patients with (a history of) malignant disease other than carcinoma of the breast;

5. Patients with hepatic disorders evidenced by elevated transamines above 3 times the upper limit of normal;

6. Patients with a renal disorder requiring renal replacement therapy;

7. Patients with a life expectancy of less than 1 year for whatever clinical condition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2003
Enrollment:	72
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL199
NTR-old	NTR236
Other	: N/A
ISRCTN	ISRCTN56637853

Study results

Summary results
N/A